Docket No. PRD2101NP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Paul J. Dunford et al.

Serial No. : 10/656,504 Art Unit:

Filed : September 6, 2003 Examiner:

For : METHOD TO TREAT ALLERGIC RHINITIS

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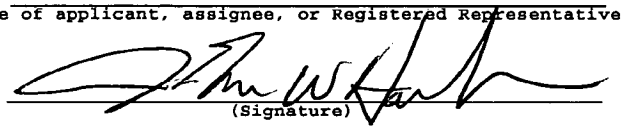
(Name of applicant, assignee, or Registered Representative)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INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ / the fee of $180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/ / the fee of $180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of $180.00 as set forth in §1.17(p).

☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☐ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the

national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i).

☐ There are no listed references which are not in the English language.

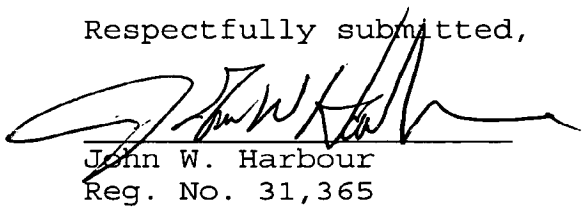
☒ The relevance of those listed references which are not in the English language is as follows: English abstracts are attached for the following patents:DE2157424A, DE4307883A1, EP0624575A1, EP0655440A2, JP01132579A2, JP5025131A, JP9124631A SU1074094A1, WO97/03965 WO99/05121 and WO01/74774A1.

☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/PRD2101/JWH. This form is submitted in triplicate.

Respectfully submitted,



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DATED: December 4, 2003

PTO/SB/08A (08-00)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 4

4	10/656,504
Filing Date	September 5, 2003
First Named Inventor	Paul J. Dunford
Group Art Unit	
Examiner Name	
Attorney Docket Number	PRD2101NP

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		USPN 4,115,569		Weber, R.-O. et al.	09-19-1978	
		USPN 4,374,990		Weber, R.-O. et al.	02-22-1983	
		USPN 5,563,142		Palmer, J.R. et al.	10-08-1996	
		USPN 5,814,644		Kulagowski, J.J. et al.	09-29-1998	
		USPN 5,891,902		Machii, D. et al.	04-06-1999	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Office[3]	Number[4]	KindCode[5]	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T[6]
		JP	01132579 √	A2	S. S. Pharmaceutical Co., Ltd.	05-25-1989	(SciFinder Abstract)	
		SU	1074094 √	A1	A. Med. Pharmacology Res. Inst.	04-23-1992	(DIALOG ® File 351 : Derwent WPI)	
		JP	5025131 √	A	Toray Industries Inc.	02-02-1993		
		EP	0548798 √	A1	Sanwa Kagaku Kenkyusho Co., Ltd.	06-30-1993		
		DE	4307883 √	A1	Westarp, Martin-Egon, Dr. med.	09-23-1993		
		WO	94/09781 √		The Upjohn Co.	05-11-1994		
		EP	0624575 √	A1	Adir et Compagnie	11-17-1994		
		EP	0655440 √	A2	F. Hoffmann-La Roche A.G.	05-31-1995		
		WO	97/03965 √		Kyowa Hakko Kogyo Co., Ltd.	02-06-1997		
		JP	9124631 √	A	Senseishiyou Chiyuuiyaku Kenki; Mitsubishi Chem. Corp.	05-13-1997		
		WO	98/01443 √		Smithline Beecham S.p.A.	01-15-1998		
		WO	99/058121 √		Laboratorios del Dr. Esteve, S.A.	02-04-1999		
		WO	01/74774 √	A1	Daiichi Pharmaceutical Co.	10-11-2001		
		WO	91/09849 √	A1	The Upjohn Company	07-11-1991		
		WO	99/09025 √	A2	Pfizer Products Inc.	02-25-1999		
		WO	01/64676 √	A2	Scios, Inc.	09-07-2001		
		EP	0318235 √	A2	Takeda Chemical Industries, Ltd.	05-31-1989		
		EP	0324431 √	A1	Fujisawa Pharmaceutical Co., Ltd.	07-19-1989		
		EP	0978512 √	A1	Societe Civile Bioproject	02-09-2000		
		DE	2157424 √	A	Chemische Werke Albert AG	05-24-1973		

Examiner		Date	

Signature		Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 4

Application Number	10/656,504
Filing Date	September 5, 2003
First Named Inventor	Paul J. Dunford
Group Art Unit	
Examiner Name	
Attorney Docket Number	PRD2101NP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		AGARWAL, A. et al. A New Synthesis of the Potent 5-HT1 Receptor Ligand, 5-Carboxyamidotryptamine (5-CT). Synth. Commun. (1993) 23(8):1101-1110	
		ALVAREZ, E.F. et al. Psychotropes Potentiels. III. Préparation des [(Hydroxy-5 ou Benzyloxy-5 indolyl)-2 carbonyl]-1 alkyl-2 hydrazines et Étude de Leur Activité Inhibitrice de la Monoamine Oxydase. Bull. Soc. Chim. Fr. (1969) (6):1932-1940	
		AMBEKAR, S.Y. Recent Developments in the Fischer Indole Synthesis. Current Science (1983) 52(12):578-582	
		BETRABET, A.M. et al. Synthesis & Pharmacology of 5-Methoxyindole-2-carboxyamides & Their 3-Formyl Derivatives. Indian J. Chem. (1970) 8:704-706	
		BHANDARI, K. et al. Agents Acting on CNS: Part XXXIII -- Synthesis of 1,2,3,4,6,7,8,12c-Octahydropyrazino[2',1' : 2,1]pyrido[4,3-b]indole & Some 2-Substituted Aminoalkylindoles. Indian J. Chem. (1979) 17B:246-249	
		DE COSTA, B.R. et al. Synthesis and Evaluation of Conformationally Restricted N-[2-(3,4-Dichlorophenyl)ethyl]-N-methyl-2-(1-pyrrolidinyl)ethylamines at sigma Receptors. 2. Piperazines, Bicyclic Amines, Bridged Bicyclic Amines, and Miscellaneous Compounds. J. Med. Chem. (1993) 36:2311-2320	
		DUBEY, R. et al. Mass Spectral Studies of 2,5-Disubstituted Benzimidazoles. Indian J. Chem. (1987) 26B:395-397	
		El-Kholy, I.E.-S. et al. Reaction of Some Coumarin and 4,6-Diaryl-2H-pyran Derivatives with Secondary Amines. J. Heterocyclic Chem. (1981) 18:105-110	
		FONT, M. et al. Indoles and Pyridazino[4,5-b]indoles as Non-Nucleoside Analog Inhibitors of HIV-1 Reverse Transcriptase. Eur. J. Med. Chem. (1995) 30:963-971	
		GARCIA, F. et al. The Synthesis of Thienopyrroles. Synthesis (1985) 143-156	
		HEMETSBERGER, H. et al. Enazides, III: Thermolysis of alpha-Azido-cinnamates. Synthesis of Indol Carboxylates. Monatsh. Chem. (1970) 101(1):161-165	
		HEMETSBERGER, H.; KNITTEL, D. Enazides, IV: Synthesis and Thermolysis of alpha-Azidoacrylates. Monatsh. Chem. (1972) 103(1):194-204	
		HUGHES, D.L. Progress in the Fischer Indole Reaction. A Review. Org. Prep. Proced. Int. (1993) 25(6):607-632	
		KETCHA, D.M. Five-Membered Ring Systems: Pyrroles and Benzo Derivatives. Prog. Heterocycl. Chem. (1999) 11:124-14	
		LOVE, B.E.; NGUYEN, B.T. A General Synthesis of 1-(Dialkylaminomethyl)indoles. Synlett (1998) :1123-1125	
		MARTINEZ, S.J.; JOULE, J.A. The Synthesis of 2,3,4,6-Tetrahydro-5-hydroxy-2,6-dimethyl-1H-pyrido-[4,3-b]carbazole; Attempts to Synthesise 2,3,4,10-Tetrahydro-5-hydroxy-2-methyl-1H-pyrido[3,4-b]carbazole. J. Chem. Soc., Perkin Trans. 1 (1979) 3155-3160	
		MONGE, A. et al. Selective Thromboxane Synthetase Inhibitors and Antihypertensive Agents. New Derivatives of 4-Hydrazino-5H-pyridazino[4,5-b]indole, 4-Hydrazinopyridazino[4,5-a]indole, and Related Compounds. J. Med. Chem. (1987) 30:1029-1035	
		MURAKAMI, Y. et al. p-Toluenesulfonic Acid and Cation Exchange Resin in Aprotic Solvent: Valuable Catalysts for Fischer Indolization. Heterocycles (1984) 22(5):1211-1216	
		NAGARATHNAM, D.; JOHNSON, M.E. A New Synthesis of 5-Bromo-DL-tryptophan. Synth. Commun. (1993) 23(14):2011-2017	
		NAKAMURA, T. et al. Molecular Cloning and Characterization of a New Human Histamine Receptor, HH4R Biochem. Biophys. Res. Commun. (2000) 279:615-620	
		PHILLIPS, M.A. The Formation of 2-Substituted Benziminazoles. J. Chem. Soc. (1928) :2393-2399	
		PRESTON, P.N. Synthesis, Reactions, and Spectroscopic Properties of Benzimidazoles. Chem. Rev. (1974) 74(3):279-314	
		RASTOGI, R.; SHARMA, S. Synthesis of 2-Substituted Benzofurans as Potential Anthelmintics. Indian J. Chem. (1982) 21B:485-487	
		ROMERO, D.L. et al. Bis(heteroaryl)piperazine (BHAP) Reverse Transcriptase Inhibitors: Structure-Activity Relationships of Novel Substituted Indole Analogues and the Identification of 1-[(5-Methanesulfonamido-1H-indol-2yl)-carbonyl]-4-[3-[(1-methylethyl)amino]-pyridinyl]piperazine Monomethanesulfonate (U-90152S), a Second-Generation Clinical Candidate. J. Med. Chem. (1993) 36(10):1505-1508	
		ROMERO, D.L. et al. Discovery, Synthesis, and Bioactivity of Bis(heteroaryl)piperazines. 1. A Novel Class of Non-Nucleoside HIV-1 Reverse Transcriptase Inhibitors. J. Med. Chem. (1994) 37(7):999-1014	
		ROMERO, D.L. et al. Targeting Delavirdine/Atevirdine Resistant HIV-1: Identification of (Alkylamino)piperidine-Containing Bis(heteroaryl)piperazines as Broad Spectrum HIV-1 Reverse Transcriptase Inhibitors. J. Med. Chem. (1996) 39(19):3769-3789	
		SALITURO, F.G. et al. 3-(2-Carboxyindol-3-yl)propionic Acid Derivatives: Antagonists of the Strychnine-Insensitive Gylcine Receptor Associated with the N-Methyl-D-aspartate Receptor Complex. J. Med. Chem. (1990) 33(11):2944-2946 This was listed incorrectly under King, F.D. in 1599 IDS 1st supplement	
		SHAFIEE, A. et al. Synthesis and Local Anesthetic Activity of Benzo[b]furan Derivatives. J. Pharm. Sci. (1978) 67(1):125-127	
		SUNDBERG, R.J.; RUSSELL, H.F. Syntheses with N-Protected 2-Lithioindoles. J. Org. Chem. (1973) 38(19):3324-333	
		SUZUKI, H. et al. Unexpected Formation of Quinolone Dervatives in Reissert Indole Synthesis. Synlett (2000) 8:1196-1198	
		TANI, M. et al. Regioselective and Non-reductive C3-Debromination of Indole Nucleus. Synlett (1996) 9:931-932	
		YAMADA, F.; SOMEI, M. A Convenient Synthetic Approach to 4-Substituted Indoles. Heterocycles (1987) 26(5):1173-1176	

		CHEMICAL ABSTRACTS, Vol. 78, No. 15, 16 April 1973 Columbus, Ohio, BUROV, YU. V. ET AL.: "Derivatives of benzofuran-2-carboxylic acids and their action on the central nervous system." XP002210361	
		CHEMICAL ABSTRACTS, Vol. 130, No. 4, 25 January 1999, Columbus, Ohio, CHANG, MAYLAND ET AL., "Absorption, distribution, metabolism, and excretion of atevirdine in the rat." XP002210368	
		SIAVOSH MAHBOOBI ET AL., "Synthetic 2-aroylindole derivatives as a new class of potent tubulin-inhibitory, antimitotic agents" Journal of Medicinal Chemistry, Vol. 44, No. 26, 2001 pages 4535-4553 XP002210359	
		CHEMICAL ABSTRACTS, Vol. 127, No. 3, 21 July 1997 Columbus, Ohio, TAKASHIMA, JUNKO: "Preparation of benzofuran derivatives as antihypertensive agents" XP002210363	
		CHEMICAL ABSTRACTS, Vol 121, No. 19, 7 November 1994, Columbus, Ohio, ZAWADOWSKI, TEODOR ET AL., "Synthesis of piperazinamides of benzofuran-2-and-3-carboxylic acids." XP002210364 & Abstract ACTA POL. PHARM., Vol. 50, No. 6 1993 pages 457-459 & DATABASE CAPLUS ONLINE CHEMICAL ABSTRACT SERVICE, Columbus, Ohio XP002210369	
		CHEMICAL ABSTRACTS, Vol. 119, No. 3, 19 July 1993 Columbus, Ohio, SHIBAYAMA, KATSUHIRO ET AL., "Preparation of piperazine or piperidine group-containing indoles and their use as anti-inflammatory, antiallergy, and anti-PAF agents." XP002210365 & JP 09325131 TORAY INDUSTRIES 16 December 1997 & DATABASE CAPLUS ONLINE CHEMICAL ABSTRACT SERVICE, Columbus, Ohio, XP002210370	
		CHEMICAL ABSTRACTS, Vol. 111, No. 19, 6 November 1989, Columbus, Ohio, KOMOTO, TERUO ET AL., "Preparation of (indolylcarbonyl) piperazines as platelet aggregation inhibitors." XP002210366 & JP 89132579 S.S. PHARMACEUTICAL CO., LTD. 25 May 1989 & DATABASE CAPLUS ONLINE CHEMICAL ABSTRACTS SERVICE, Columbus, Ohio XP002210371	
		CHEMICAL ABSTRACTS, "Derivatives of benzofluran-2-carboxylic acids and their action on the central nervous system" XP-002210367	
		HOFSTRA, C. L. et al. Histamine H4 Receptor Mediates Chemotaxis and Calcium Mobilization of Mast Cells. J. Pharmacol. Exp. Ther. (2003) 305(3):1212-1221.	
		GANTNER, F. et al. Histamine H4 and H2 Receptors Control Histamine-Induced Interleukin-16 Release from Human CD8+ T Cells. J. Pharmacol. Exp. Ther. (2002) 303(1):300-307.	
		O'REILLY, M. et. Al. Identification of a histamine H4 receptor on human eosinophils-role in eosinophil chemotaxis. Journal of Receptors and Signal Transduction (2002) 22(1-4):431-448	
		ARRANG, J.-M. et al. Auto-inhibition of Brain Histamine Release Mediated by a Novel Class (H3) of Histamine Receptor. Nature (1983) 302:832-837	
		ASH, A.S.F.; SCHILD, H.O. Receptors Mediating Some Actions of Histamine. Br. J. Pharmac. Chemother. (1966) 27:427-439	
		BARGER, G.; DALE, H.H. Chemical Structure and Sympathomimetic Action of Amines. J. Physiol. (1910) 41:19-59 Reprinted in Adventures in Physiology; Sir Henry H. Dale, Ed.; The Wellcome Trust: London, 1965; pp 67-98	
		BLACK, J.W. et al. Definition and Antagonism of Histamine H2-Receptors. Nature (1972) 236:385-390	
		GANTZ, I. et al. Molecular Cloning of a Gene Encoding the Histamine H2 Receptor. Proc. Natl. Acad. Sci. USA (1991) 88:429-433	
		HILL, S.J. et al. International Union of Pharmacology. XIII. Classification of Histamine Receptors. Pharmacol. Rev. (1997) 49(3):253-278	
		LIU, C. et al. Cloning and Pharmacological Characterization of a Fourth Histamine Receptor (H4) Expressed in Bone Marrow. Mol. Pharmacol. (2001) 59(3):420-426	
		LOVENBERG, T.W. et al. Cloning and Functional Expression of the Human Histamine H3 Receptor. Mol. Pharmacol. (1999) 55(6):1101-1107	
		MORSE, K.L. et al. Cloning and Characterization of a Novel Human Histamine Receptor. J. Pharmacol. Exp. Ther. (2001) 296(3):1058-1066	
		NGUYEN, T. et al. Discovery of a Novel Member of the Histamine Receptor Family. Mol. Pharmacol. (2001) 59(3):427-433	
		ODA, T. et al. Molecular Cloning and Characterization of a Novel Type of Histamine Receptor Preferentially Expressed in Leukocytes. J. Biol. Chem. (2000) 275(47):36781-36786	
	U	RAIBLE, D.G. et al. Pharmacologic Characterization of a Novel Histamine Receptor on Human Eosinophils. Am. J. Respir. Crit. Care Med. (1994) 149:1506-1511	
	U	YAMASHITA, M. et al. Expression Cloning of a cDNA Encoding the Bovine Histamine H1 Receptor. Proc. Natl. Acad. Sci. USA (1991) 88:11515-11519	
	U	ZHU, Y. et al. Cloning, Expression, and Pharmacological Characterization of a Novel Human Histamine Receptor. Mol. Pharmacol. (2001) 59(3):434-441	
	U	BIGGE, C.F. et al. New Preparations of the N-Methyl-D-Aspartate Receptor Antagonist, 4-(3-Phosphonopropyl)-2-Piperazinecarboxylic Acid. Tetrahedron Lett. (1989) 30(39):5193-5196	

Examiner Signature		Date Considered	

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